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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,916	09/26/2003	T. Debuene Chang	CHANG-001	7353
48888	7590	01/06/2006		
TOBIN, CARBERRY, O'MALLEY, RILEY, SELINGER, P.C.			EXAMINER	
43 BROAD STREET			APANIUS, MICHAEL	
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NEW LONDON, CT 06320			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

T22

Office Action Summary	Application No.	Applicant(s)	
	10/673,916	CHANG ET AL.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03292004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to because the drawings are hand-drawn and all lines are not of uniform thickness (for instance, parts of figure 10 are not uniformly well-defined). Furthermore, the rectangular boxes in figure 3 must be provided with descriptive labels (for instance, element 52 should be labeled --Battery--). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: --A urinary diagnostic system with an implantable sensing device--.

6. At paragraph 41, line 5, the use of the trademark BLUETOOTH has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. The disclosure is objected to because of the following informalities:

- a. At the abstract, line 1, "is disclosed. The diagnostic system" should be deleted.
- b. At paragraph 26, line 2, one recitation of "processing device" should be deleted.
- c. At paragraph 37, line 11, "two-sensing device measurement" should be --two sensing device measurements--.
- d. At paragraph 44, line 11, "urethra 24" should be --urethra 22--.
- e. At paragraph 50, line 1, "112 and 120" should be --102 and 122--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. At claims 1, 11 and 20, a deployable housing is claimed to completely enclose the sensing device. The meaning of this limitation is unclear because it is inconsistent with the specification and drawings. At paragraph 27, line 1, the housing is alternatively named a cage. In the drawings, the housing "30" appears to be a cage comprising bars with open space in between the bars. Therefore, the housing does not completely enclose the sensing device "28" because of the open space located between the bars of the housing. Furthermore, it is this open space that allows fluid to flow through the housing.

7. At claim 11, line 1, "a method for using a sensing device disposed in a body part" is claimed. However, the steps of the method include steps occurring before the sensing device is disposed or inserted in a body part. Therefore, it is unclear if the steps occurring before the sensing device is disposed in a body part are part of the claim limitations because only "a method for using a sensing device disposed in a body part" is claimed.

8. At claim 16, line 1, "said disposer" lacks antecedent basis. Note that claim 11 does not previously recite a disposer.

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9. Claim 21 depends from claim 19 but claims a diagnostic system. It appears that claim 21 was intended to depend from claim 20 and will be treated as such in this office action.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-10, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Silver (US 6,442,413).

12. In regards to claims 1, 20 and 21, Silver discloses a diagnostic system, comprising: a sensing device (sensing surface; see column 11, lines 14-16) having a retrieval wire (antenna; see column 11, lines 7-8), said sensing device configured to collect data; a deployable housing (semi-permeable membrane; see column 11, lines 33-38), said housing having a body defining an interior and an exterior, said housing is configured to allow fluid to flow through said housing, wherein said housing completely encloses said sensing device; a disposer (figure 7B) for disposing said housing enclosing said sensing device in a body part; and a processing device (figure 1B) configured to receive said data from said sensing device. Note that the housing is

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deployable into the body via the disposer. In regards to claim 2, the sensing device can be a thermal sensing device (column 13, lines 31-33). In regards to claim 3, the processing device has an RF transceiver that is a passive transceiver. As the processing device has an antenna (34) and a transmitter (44) within a single remote circuit (32), the processing device is deemed to have a RF transceiver because the elements for receiving and transmitting are within the same remote circuit. In regards to claim 4, the retrieval wire is configured to operate as an antenna (column 11, lines 7-8). In regards to claim 5, the housing can be made from a polymer (column 11, lines 38-44). In regards to claim 6, the disposer is a catheter mechanism comprising a sheath (108) and a push bar (110). In regards to claim 7, the data is transmitted by radio frequency (column 11, line 5). In regards to claim 8, the sensing device is accessible for retrieval from an exterior of a body. Note that anything put into the body may be retrieved in some manner or another. In regards to claim 9, a urine sensing device (24) is disposed proximate said retrieval wire. Note that the sensing device is capable of detecting urine that is contacted with the sensing device by sensing an analyte of interest within urine. Due to the fact that the urine sensing device is connected to the sensing device, the urine sensing device is capable of sensing urine. In regards to claim 10, the processing device is configured to transmit data (column 12, line 4-7).

Allowable Subject Matter

13. Claims 11-19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

14. The following is a statement of reasons for the indication of allowable subject matter: no prior art of record teaches or fairly suggests a method for using a sensing device disposed in a body part as set forth in claims 11-19.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,846,191 discloses a device for chronic measurement of internal body pressure. US 6,159,156 discloses a pressure sensor for use in an artery. US 6,682,490 discloses an apparatus and method for monitoring a condition inside a body cavity. US 2002/0138009 discloses an implantable sensor with wireless communication. US 2003/0136417 discloses an implantable wireless sensor.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA


CHARLES MARMOR
PRIMARY EXAMINER